

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY	)	
AVERAGE WHOLESale PRICE	)	
LITIGATION	)	MDL No. 1456
	)	Civil Action No. 01-12257-PBS
	)	
<b>THIS DOCUMENT RELATES TO:</b>	)	Hon. Patti Saris
	)	
<i>United States of America ex rel. Ven-a-Care of</i>	)	Magistrate Judge Marianne Bowler
<i>the Florida Keys, Inc. v. Abbott Laboratories,</i>	)	
<i>Inc.,</i>	)	
CIVIL ACTION NO. 06-11337-PBS	)	

**MEMORANDUM BY THE UNITED STATES  
IN RESPONSE TO ABBOTT'S OBJECTIONS TO  
MAGISTRATE JUDGE BOWLER'S FEB. 1, 2008 ORDERS**

Abbott Laboratories Inc. (Abbott) has objected to the rulings by Magistrate Judge Bowler resulting from three motions to compel it filed against the United States. These motions relate to (1) the Government's responses to Abbott's Request For Production (RFP) numbers 37 and 38 (Dkt. 4790, (2) documents from a CMS employee named Ira Burney (Dkt. 4892), and (3) "cross-cutting" privileged documents which Abbott contends should be submitted to the magistrate for *in camera* review (Dkt. 4901) ("motion for *in camera* submission"). Magistrate Judge Bowler denied each of Abbott's motions to compel.

The first and second motions noted above, relating to Abbott's RFPs 37 and 38 and the documents from Ira Burney, were properly denied because the magistrate judge was clearly correct in ruling that the burden associated with the production of certain documents outweighs any potential evidentiary value the documents may have.

With respect to the motion for *in camera* submission, the instant objection by Abbott is largely a repeat of arguments previously raised with, and rejected by, this Court when Abbott

appealed an August 13, 2007 Order by the magistrate which denied Abbott's motion for the production of material covered by the deliberative process privilege. Moreover, Abbott's purported need for the type of material which it suggests ought to be submitted to the magistrate for review, were any such material to exist, is specious in light of controlling law in this circuit and this Court's seminal ruling in November 2006 regarding how the term "AWP" shall be construed. Finally, the facts and circumstances asserted by Abbott relating to both the Government's production of documents and the type of material submitted for *in camera* review are not in accordance with either the actual production by the United States or the Government's compliance with this Court's Order of November 9, 2007, which required the Government to submit particular classes of material to the magistrate.

The objections by Abbott to Magistrate Judge Bowler's orders should be denied

#### **I. Background - Legal and Factual Backdrop to Current Discovery Dispute**

The United States has brought this action principally under the False Claims Act, 31 U.S.C. § 3729 ("FCA"), for damages to the Medicare and Medicaid programs. In order to prevail on its FCA claims, the United States must show that Abbott (1) reported false prices and (2) did so "knowingly," as that term is defined in the FCA. The Government's complaint also states claims for common law fraud and unjust enrichment. Both Medicare and most Medicaid programs used published Average Wholesale Prices (AWPs) as the pricing points upon which the payment amounts for individual claims were based. The United States alleges that Abbott knowingly created false AWPs that served as the basis for the Government's payments to Abbott's customers, and in some instances, Abbott itself.

In a summary judgment order issued in the MDL on November 2, 2006, this Court determined that the term "AWP" would be construed pursuant to its plain language, and held that

AWP “means the average price at which wholesalers sell drugs to their customers, including physicians and pharmacies.” *In Re Average Wholesale Price Litig.*, 460 F. Supp. 2d 277, 278 (D. Mass. 2006). The United States’ First Amended Complaint (FAC) pertains to, essentially, five products<sup>1</sup> for which Abbott created what this Court has described as “mega-spreads.”<sup>2</sup> *See In Re Average Wholesale Price Litig.*, 491 F. Supp. 2d 20, 40-41 (D. Mass. 2007). In light of the November 2006 summary judgment ruling, there is no real dispute as to whether Abbott reported false prices to the compendia which published Abbott’s AWP’s for the mega-spread drugs in the FAC, given that Abbott has never claimed that its published AWP’s for the drugs here were equal to or anywhere near the average prices at which those drugs were purchased by Abbott’s customers. Indeed, the Court has already stated that creation of a “mega-spread,” in and of itself, “constitutes egregious misconduct” without even considering whether a defendant marketed such a spread to customers. *See In Re Average Wholesale Price Litig.*, 491 F. Supp. 2d at 95. Accordingly, the principal issue that remains to be litigated in this case concerns *Abbott’s knowledge* – that is, whether Abbott had actual knowledge, acted recklessly, or was deliberately ignorant with respect to the falsity of the prices it reported to the compendia.

## **II. Motions to Compel Material Responsive to RFPs 37/38 and from Ira Burney**

### **A. Abbott’s RFPs and the Materials Produced by the U.S.**

At this juncture, Abbott has served 142 RFPs on the United States. Whole categories of Abbott’s RFPs concern the Government’s awareness of actual drug prices and how the emerging

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<sup>1</sup> The five pharmaceutical products are: dextros and sodium chloride solutions, sterile water, vancomycin and acyclovir sodium.

<sup>2</sup> The drugs in this suit against Abbott, which carried spreads from roughly 275 up to 1784 percent, exceed even the upper range of “mega-spreads” described by the Court. Most of the sued-upon spreads exceed 700 percent. *See United States’ FAC*, Ex. 1 (Dkt. 4281)

evidence of AWP inflation impacted federal payment policies. Abbott's motion to compel pertains to particular sub-categories of material responsive to just two RFPs – numbers 37 and 38. Abbott's RFP 37, in pertinent part, requests documents from 1965 through 2001 "concerning the promulgation of any contemplated, proposed, or actual federal legislation, regulation, or policy concerning payment for drugs under Medicare or Medicaid, including any comments, suggestions, [or] criticisms . . . related to such legislation, regulation, or policy, including but not limited to those listed on [an] attached Schedule B." The regulations on Schedule B relate to a range of issues, including payment for drugs and the Medicare Prospective Payment System for Hospital Outpatient Services. Abbott's RFP 38 requests documents "relating to actions taken or considered by [the Government] to change the methodology to pay for drugs under Medicare Part B or Medicaid after becoming aware that AWP exceeded the average acquisition costs of Providers for drugs, including the Subject Drugs" (i.e. those in the FAC).

The Government objected to both of the RFPs as overly broad, vague, unduly burdensome, seeking documents which are publicly available (and thus accessible to defendants) and seeking material that is neither relevant to any claims or legitimate defenses, nor reasonably calculated to lead to the discovery of admissible evidence. The Government also objected that the requests seek documents protected by the deliberative process and attorney-client privileges.

Notwithstanding these objections, the Government has produced tens of thousands of pages of material responsive to these requests. For a description of the Government's production to date, as it relates to the RFPs at issue here, the United States respectfully refers the Court to the opposition brief submitted to the magistrate judge. *See* Memorandum by the United States in Opposition to Abbott's Motion to Compel Responses to Document Request Nos. 37 and 38 (Dkt. 4869), at 4-7.

As made clear in the briefs filed with the magistrate, the Government has produced, or agreed to make available, material from two particular sources of interest to Abbott. One source is CMS's Office of Legislation. To date, the Government has produced over 4,200 pages of material from this office and expects to produce another 1,200 pages by next week. Ira Burney, whose files are the subject of a separate motion to compel by Abbott, is currently, and for many years has been, employed at the Office of Legislation. Accordingly, Abbott's motion to compel the production of documents from this individual concerns a subset of material from the Office of Legislation. The parties appear to have reached a common understanding that Abbott's two motions to compel essentially overlap.

The second source of interest to Abbott is the files maintained by CMS relating to rulemakings. The Government agreed to make available for inspection CMS files which constitute "The Official Rulemaking Records" for those items on Abbott's Schedule B (listing the regulations covered by RFP No. 37). Under CMS's records disposition authority, the "Official Rulemaking Record" consists of the published proposed rule, public comments received in response to the proposed rule, the public comment log prepared by the record keeping office, and any studies associated with the rulemaking. *See* Declaration of Lisa Parker, ¶5.<sup>3</sup>

**B. The United States' Objections and the Material Withheld from Production**

In addition to maintaining an Official Rulemaking Record, CMS also maintains a category of material designated the "Rulemaking Support File" – a class of documents which the Government has declined to produce. The Rulemaking Support Files consist of internal,

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<sup>3</sup> The Declaration of Lisa Parker was appended as Exhibit 1 to the Memorandum by the United States in Opposition to Abbott's Motion to Compel Responses to Abbott's Document Requests Nos. 37 and 38 (Dkt. 4869).

pre-decisional documents and drafts, including drafts of the rules, internal comments received on the drafts, regulation logs, regulation specifications, preliminary actuarial estimates, internal recommendations and briefing papers. Prior to 2005, internal, pre-decisional documents and drafts that are now maintained in the Rulemaking Support File were considered part of the Official Rulemaking Record. CMS was given approval by the National Archives & Records Administration in 2005 to change its policy so that it could segregate and maintain the Rulemaking Support Files apart from the Official Rulemaking Record. As indicated in the declaration of the CMS official cited above, CMS considers that the internal, pre-decisional documents and drafts reflecting the views and opinions of CMS personnel contained in the Rulemaking Support files to be an integral and deliberative part of the regulatory process at CMS. *See Declaration of Lisa Parker*, ¶ 13.

Abbott also has moved to compel material from CMS's Office of Legislation. This office is responsible for responding to issues brought to the attention of CMS by any Member of Congress. Additionally, the Office of Legislation 1) provides leadership on Medicare, Medicaid and State Children's Health Insurance Program (SCHIP) legislative strategies and 2) advances the policy development process through the analysis and review of health care initiatives and issues. *See Declaration of Donald Johnson*, ¶ 3.<sup>4</sup> The staff at the Office of Legislation reviews and analyzes CMS legislative and budget initiatives and makes recommendations to higher level officials concerning the costs and impact of these proposals. They also prepare reports and recommendations for the staff in CMS's Center for Medicare Management, as well as the CMS

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<sup>4</sup> The Declaration of Donald Johnson was appended as Exhibit 4 at Dkt. 4869.

Administrator and other Departmental officials, about potential modifications to existing and proposed policies that will improve the operation of CMS programs.

The Government has produced non-privileged material from the Office of Legislation. The files that have been withheld from production contain documents with hand-written notes, e-mails, and draft CMS memoranda, as well as drafts of legislation, regulations, and OIG and GAO Reports with hand-written marginalia by Office of Legislation staff. In short, the documents reflect the thoughts, opinions and recommendations of an office concerned, virtually exclusively, with the development and refinement of policy.

### **C. Points and Authorities**

#### **1. The Scope of Permissible Discovery Under the Federal Rules**

Rule 26 (b)(2) of the Federal Rules of Civil Procedure places general limitations on the discovery burden that may be imposed by one party on another. In relevant part, the rule provides that: “The frequency or extent of use of the discovery methods otherwise permitted under these rules and by local rule shall be limited by the court if . . . the burden or expense of the proposed discovery outweighs its likely benefit, taking into account the needs of the case, the amount in controversy, the parties’ resources, the importance of the issues at stake in the litigation, and the importance of the proposed discovery in resolving the issues. . . .” Fed. R. Civ. P. 26(b)(2). The limitation in Section (b)(2) “was added by the 2000 amendments to the rules to ‘emphasize the need for active judicial use of subdivision (b)(2) to control excessive discovery.’” *Gill v. Gulfstream Park Racing Ass’n Inc.*, 399 F.3d 391, 400 n. 5 (1st Cir. 2005). Significantly, “[d]iscovery of both privileged and unprivileged information may be limited by Rule 26(b)(2)(b).” *Id.* at 400.

In a similar vein, Rule 26(c) authorizes a court, upon a showing of good cause, to make “any order which justice requires” to protect the target of a discovery request from “annoyance, embarrassment, oppression, or undue burden or expense.” *Id.* at 402 (“Rule 26(c) is highly flexible, having been designed to accommodate all relevant interests as they arise”). The Rule specifically contemplates an order “that certain matters not be inquired into, or that the scope of the disclosure or discovery be limited to certain matters.” The First Circuit has explained that “the ‘good cause’ standard in the Rule is a flexible one that requires an individualized balancing of the many interests that may be present in a particular case.” *Id.* The privileged nature of a category of requested information constitutes good cause for an order limiting discovery. *Norfolk v. United States Corps of Army Eng’s*, 968 F.2d 1438, 1442, 1463 (1st Cir. 1992) (affirming issuance of protective order for privileged material); *see also, Ken's Foods, Inc. v. Ken's Steak House, Inc.*, 213 F.R.D. 89, 94-98 (D. Mass. 2002) (denying motion to compel on grounds that common interest privilege protected responsive documents).

Finally, each of these principles - relevance and privilege - operates separately. Irrelevant material is insulated from discovery under Rule 26(b) regardless of whether it is also protected from production by privilege. *Gulfstream Park Racing Ass’n Inc.*, 399 F.3d at 400.

2. Abbott Is Not Entitled to Burdensome Discovery of Irrelevant and Privileged Material

At the center of Abbott’s Objections is the assertion that the documents at issue “concern *why* CMS used an AWP-based system, and the pros and cons of alternative methodologies that were considered and rejected.” Abbott’s Objections to Magistrate Bowler’s Feb. 1, 2008 Orders (“Abbott Obj.”), at 5 (emphasis in original). According to Abbott, this material could help resolve “the dispositive question of *why* the Government did not do anything about its payment

methodology in light of [its] knowledge of [the existence of AWP spreads].” *Id.* at 16 (emphasis in the original). Abbott’s purported need for such material rests on several flawed premises.

First, Abbott’s assertion that the Government did nothing in response to abusive AWP reporting practices is obviously incorrect in light of the statutory changes effected by the Medicare Modernization Act of 2003, as well as the other efforts undertaken by CMS prior to the passage of the MMA to respond to the problem of AWP inflation. *See In Re Average Wholesale Price Litig.*, 491 F. Supp. 2d at 41-44. Second, the Government’s continued reliance on an AWP-based payment system that turned out to be susceptible to costly abuse cannot insulate Abbott from liability for its role in abusing the system. *Id.* at 94. Seeking to shift attention from its own conduct, Abbott contends this case turns on why the Government, for a period of time, continued to use that system. This case, however, is ultimately about Abbott’s conduct – more specifically, about Abbott’s practice of reporting false prices for its drugs and Abbott’s scienter in so doing.

Rule 26 places express limits on the scope of permissible discovery. First, the rule allows discovery only as to non-privileged matters. F.R.C.P. 26 (b)(1). Second, it allows a court to limit discovery “when the burden of the proposed discovery outweighs its likely benefit,” taking into account the needs of the case and the importance of the discovery in resolving issues in the litigation. F.R.C.P. 26(b)(2). The Court should deny Abbott’s objections because the material in question is both irrelevant and protected by the deliberative process privilege. Abbott cannot establish that it has any need for the material in light of both the Court’s seminal rulings on key legal issues in this case and underlying legal principles. Moreover, as explained more fully in the briefing before the Magistrate, Abbott has been provided with, or given access to, documents which detail what the Government knew about prescription drug pricing and the spreads between

AWP and actual acquisition costs. *See* Mem. by the United States in Opposition to Abbott's Motion to Compel Responses to Document Requests Nos. 37 and 38, at 4-7. Finally, as the Magistrate recognized, the burden associated with production of this material outweighs any legitimate benefit that can be achieved by compelling its production.

a. Abbott's Objections Relate to Privileged Material

Abbott's motion to compel was directed at two very particular categories of material: documents which reflect the deliberations of HHS personnel concerning a) regulations CMS was promulgating and b) legislation under consideration by Congress and other policy initiatives under consideration by the agency. The case law supporting the deliberative process privilege has been extensively set out in prior briefs by the United States. Abbott's Objections to the magistrate's Order denying Abbott's challenge to the invocation of the privilege by the United States were denied in November 2007. Abbott's current objections appear to be an attempt to relitigate an issue already decided by the Court - which is, whether the Government can invoke the deliberative process privilege when it is a plaintiff in a civil case.

For the most complete statement of its position regarding this privilege, the United States respectfully refers the Court to the United States' Opposition to Defendant Abbott Laboratories, Inc.'s Renewed Motion to Compel Evidence Withheld under the Deliberative Process Privilege (Dkt. 4076). It bears noting that the governmental interest protected by the deliberative process privilege is clearly implicated with respect to the Rulemaking Support Files to which Abbott demands access. These files are deemed to contain a particularly sensitive category of information by virtue of the authority given to CMS to segregate that type of material from the official rulemaking record. The policy of not releasing these files in response to Freedom of

Information Act requests points up the agency's concern about the sensitive nature of the deliberative material and its interest in restricting its dissemination. *See* Declaration of L. Parker, ¶ 7. Weighed against that clear expression of concern, there is no minimally sufficient reason for the Court to reconsider its November 9, 2007 Order rejecting Abbott's prior attempts to obtain privileged material in this case.

b. Abbott's Objections Involve Issues Already Resolved by the Court or First Circuit Precedent

The lack of relevance of the material covered by Abbott's motion is pertinent to two issues. First, under 26(b)(2), a party may be relieved from responding to discovery requests which have no potential to affect the resolution of any legitimate issue in the case. Second and distinct from the first question, were the Court to move beyond consideration of the threshold Rule 26 question and find that there was some minimal relevance to the material in question, in order to resolve the Government's claim of privilege, the Court would still need to balance the public interest in protection of deliberative material against a party's particularized need for the information in the case. *See, e.g., Committee for Nuclear Responsibility, Inc. v. Seaborg*, 463 F.2d 788, 791 (D.C. Cir. 1971). As the magistrate recognized, Abbott cannot establish that it has a sufficient need for the information it is seeking.

On November 2, 2006, after over four and a half years of litigation in this MDL, this Court determined, *as a matter of law*, that the term "AWP" would be construed pursuant to its plain language, and held that the term "means the average price at which wholesalers sell drugs to their customers, including physicians and pharmacies." *In Re Average Wholesale Price Litig.*, 460 F. Supp. 2d at 278. The Court thus laid to the rest the major issue that had been in contention in the MDL since its inception. Earlier this year, the Court expressly relied on this holding when

entering final judgment against three other defendants in the MDL following a bench trial. *See In Re Average Wholesale Price Litig.*, 491 F. Supp. 2d at 94.

In addition to the impact of these decisions by the Court, Abbott would not be entitled to the information it is seeking in light of clear First Circuit precedent regarding regulatory interpretation. In *United States v. Lachman*, the Court of Appeals held that any interpretive issue relating to a regulation is resolved through reference to the official public record. 387 F.3d 42, 54 (1st Cir. 2004). Any issue about Governmental intent, whether it be in changing a policy or refraining from a policy change, is not resolved by reference to the predecisional deliberations of individuals. As the First Circuit made clear, “non-public or informal understandings of agency officials concerning the meaning of a regulation are . . . not relevant.” *Id.* The “non-public understanding[s] [of individual government officials] of the regulation do not remotely satisfy the requirements of formality and public accessibility” and are not entitled to any deference. *Id.* *See also United States ex rel. Wright v. Agip, et al.*, No. 03-Cv-00264 at 7-9 (E.D. Tex. June 29, 2007) (denying motion to compel deposition of Government personnel regarding their understanding of regulations, and holding that “personal opinions of agency employees that were never communicated to a Defendant are simply irrelevant to either issues of falsity or knowledge”).<sup>5</sup>

Abbott does not make any bones about whether it is seeking deliberative material from CMS. With respect to what information CMS had in hand during the relevant time period, the Government has produced abundant material relating to what the Government knew about actual drug pricing, such as OIG inspections and audits and associated workpapers.<sup>6</sup> In this situation, it

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<sup>5</sup> The *Agip* decision is appended as Exhibit 5 at Dkt. 4869.

<sup>6</sup> *See* Mem. by the U.S. in Opposition to Abbott’s Motion to Compel Responses to Document Request Nos. 37 and 38, at 4-7 (Dkt. 4869).

is clear that Abbott is not trying to discover what information the Government acquired about drug prices but, rather, is trying to find out what particular CMS officials who contributed to the policy deliberations personally thought about factual information collected by the Government in the context of various policy initiatives. That latter category of information is plainly irrelevant under *Lachman*.

Furthermore, the Court already has addressed the issue of why the Government continued to use AWP as the benchmark for drug payments despite evidence that AWPs reported by some manufacturers for certain drugs were not reflective of market prices. The June 21 Findings and Conclusions describe the “opaque” nature of pharmaceutical pricing information for physician-administered drugs such as those sold by Abbott (*In Re Average Wholesale Price Litig.*, 491 F. Supp. 2d at 40), and the difficulties in devising non-AWP payment systems (*id.* at 91) despite the Government’s emerging recognition of the vulnerability of its payment systems and the need to develop an alternative “pragmatic pricing methodology to handle millions of annual drug transactions.” (*id.* at 40-41, 91). The Court also described the Government’s efforts to grapple with the problem created by the abusive practices of certain drug manufacturers. *Id.* at 41-46. In particular, the Court found that the reason it took years for Medicare to “devise an alternative pricing structure [was] because of the complexity of increasing the prices paid for physician services.” *Id.* at 91. The Court’s use of analogy to describe the challenge faced by the entities paying beneficiary drug claims (“shifting the pricing paradigm from AWP to another approach is like turning the RMS Queen Elizabeth”) was particularly apt. *Id.*

Finally, Abbott, by attempting to shift the focus to the Government’s action or inaction with respect to the potential abuse of its drug payment system, is yet again seeking to deflect attention from its own conduct in creating the problem which the Government then purportedly

failed to rectify with sufficient dispatch. The proposition that the Government's awareness that one of its programs may be illegally exploited and that its failure to redesign the program in response thereto somehow restricts its ability to seek redress of fraud is completely without any support in False Claims Act jurisprudence. No court has ever held that the United States is estopped from bringing an FCA action because it refrained from scrapping a program which may be susceptible to fraud and abuse. *See, e.g., id.* at 94 (finding that, although by the late 1990s "the government understood that AWP did not represent a true average of wholesale prices,. . . this knowledge does not exonerate defendants"). The premise upon which defendant's discovery and motions to compel are based has no foundation in law or logic. Given the complete lack of relevance, there is no sufficient reason to impose on the Government the burden of further reviewing, logging, or producing this material.

c. The Facts Asserted in Abbott's Objections are Not Accurate

Abbott's Objections contain two statements which require correction and clarification. Abbott, first, states that "the Government has not produced a scrap of non-public or internal material from [the Office of Legislation and Rulemaking Support Files ]. Abbott Obj. at 15. The statement, as it pertains to the Office of Legislation, is incorrect. The Government has produced thousands of pages of internal material from this source. The Government has withheld internal *deliberative* material. As for the Rulemaking Support Files, it is true that material from these files has been withheld in its entirety, but it is important to note that Official Rulemaking Records have been available for review by Abbott.

Second, Abbott states that "the Government has actually produced just roughly two boxes of documents from CMS's Central Office..." *Id.* at 16. This statement is inexplicable in light of the level of information being provided to Abbott during the Government's rolling production of

documents in this matter. With every transmittal of material to Abbott over the past year, the Government has provided extensive detail regarding the particular source for each batch of documents produced. *See* examples of transmittal letters appended hereto as an exhibit. To date, the Government has produced over 20,000 pages of material from CMS's central office and will be producing additional documents in the coming week.<sup>7</sup> (This is out of a total Government production of approximately 265,000 pages of documents (a page count which does *not* include records made available for inspection (but which have not been imaged and produced on compact disc) or claims information produced in a data format.)

d. The Government's Assertion of Privilege is Sufficient and Effective

In moving to compel production of the material in question, Abbott also asserts that the Government has stated a "blanket" assertion of the deliberative process privilege and that such a purported "approach is improper under established case law."<sup>8</sup> As demonstrated to the magistrate, however, the United States has not stated a blanket assertion of privilege and the manner in which the Government has asserted the privilege is entirely appropriate. For the sake of brevity, the United States respectfully refers the Court to the fuller discussion of this issue in the brief submitted to Magistrate Judge Bowler. *See* Dkt. 4869, at 17-19. In any event, the lack of

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<sup>7</sup> This number reflects the volume of material covered by the following Bates prefixes (for each prefix, the Government has previously provided Abbott with source information): HHC001, HHC002, HHC003, HHC004, HHC021, HHC025, HHC901, HHC902, HHC903, HHC904, HHD004, HHD043, HHD046, HHD058, HHD063, HHD066, HHD069, HHD078, HHD079, HHD081, HHD082, HHD083, HHD085, HHD092, HHD096, HHD097, HHD099, HHD101, HHD102, HHD109, HHD119, HHD128, HHD129, HHD130, HHD132, HHD133, HHD134, HHD136, HHD138, HHD149, HHD166, HHD170, HHD172.

<sup>8</sup> Abbott's Objections to Magistrate Judge Bowler's Feb. 1, 2008 Order, at 18.

relevance of this material renders Abbott's objections regarding the manner in which the privilege has been asserted moot – which is presumably why the Magistrate did not reach this issue.

### **III. Motion to Compel Submission of “Cross-Cutting” Evidence**

Abbott requests that the Government be compelled to submit “cross-cutting documents to the Court for *in camera* review. According to Abbott, “cross-cutting documents” are ones which, as distinct from those which specifically mention Abbott drugs, pertain to “categories of products into which Abbott's products fall.” Motion for *In Camera* Submission, at 12. According to Abbott, the United States has asserted that the only documents which it will submit for *in camera* review to the Magistrate are those which “explicitly reference Abbott.” *Id.* at 2. There are two fundamental problems with Abbott's objection on this issue. The first one is that the position which Abbott attributes to the United States is simply not one which the Government has been implementing. The second problem is that Abbott has previously sought the relief now requested with this Court and the arguments now repeated by Abbott have already been resolved by the Court's Order of November 9, 2007.

#### **A. Briefing Re: Prior Motion to Compel Production of Privileged Material**

If the assertions and arguments stated in support of Abbott's current objections sound familiar, it is because Abbott has already made them to the Court. Virtually all the arguments made in support of Abbott's latest objections are a rehash of points covered last fall when Abbott objected to the Magistrate's ruling on its motion to compel documents withheld based on the deliberative process privilege. Accordingly, the procedural history is pertinent to the present objections and will be briefly recapped below.

In March 2007, Abbott renewed its efforts to compel the production of documents which the Government withheld based on the deliberative process privilege.<sup>9</sup> During the litigation before the magistrate judge, the Government estimated that approximately 60 of the documents which had been withheld related to Abbott drugs. The magistrate judge ultimately issued a Order denying Abbott's motion "except to the extent that the approximately 60 documents that expressly reference Abbott Laboratories, Inc. and/or the subject drugs as well as those documents that concern the government's knowledge of the common use of spreads with respect to published AWP's shall be produced." Electronic Order of Aug. 13, 2007.

Both sides objected to the Order by the magistrate judge. Abbott objected that the phrase "common use" of spread as used in the August 13 order could be construed too narrowly and asked this Court to clarify that the phrase should "be understood to include all evidence of the Government's knowledge of the differences between published AWP's and provider acquisition costs."<sup>10</sup> Abbott complained that the magistrate's phrasing would allow the Government to argue that words "use of spread" would "require it to produce only those documents that concern its knowledge of 'marketing the spread.'" *Id.* Abbott further complained that "requiring production of documents that 'expressly reference' [Abbott] is too narrow" because documents which "likely do not 'expressly reference' Abbott may "nonetheless affect the Subject Drugs because those drugs fall within the categories of products mentioned in the documents."<sup>11</sup> Indeed, the language used by Abbott when objecting to the August 13, 2007 Order is the same as that used in the

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<sup>9</sup> See Dkt. 3959.

<sup>10</sup> See Abbott's Objections to Magistrate Judge Bowler's Aug. 13, 2007 Order (Dkt. 4698), at.15.

<sup>11</sup> *Id.* at 18.

instant Objections. Last fall, Abbott argued that by withholding documents relating to AWP policymaking, “the Government would prevent the jury from learning *why* CMS used AWP” and that such evidence “sheds light on why Government officials continued to rely on published drug prices despite extensive knowledge that they did not represent a reliable indication of acquisition costs.”<sup>12</sup>

The Government, for its part, objected on the basis that the August 13 Order (1) required immediate production of 60 documents to Abbott, as opposed to *in camera* review by the Court and (2) was over broad because it covered documents relating to the “common use of spreads,” without being limited to Abbott or the Subject Drugs (i.e. the drugs in the Complaint by the United States).

On November 9, 2007, this Court ruled on the cross objections. The United States believes that, fairly read, the Court’s Order generally upheld the objections by the United States because it required (1) *in camera* review of documents rather than production directly to Abbott and (2) covered only documents relating to the Government’s knowledge of (a) a spread for the drugs in the complaint against Abbott or (b) the marketing of the spread by Abbott. Specifically, the Court stated that the “government must produce for *in camera* inspection by the magistrate judge all documents which relate to its knowledge of a “spread” for Abbott’s drugs *at issue in this litigation* or its knowledge of *Abbott’s marketing* of the spread for any of *its drugs*.” (Emphasis supplied.) The Court further stated that the objections to the magistrate judge’s order were “otherwise denied.”

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<sup>12</sup> *Id.* at 13 (emphasis in original).

**B. The Government's Submission of Documents for *In Camera* Review**

In response to the November 9 Order, the United States submitted 21 documents to the magistrate judge for *in camera* review, as well as a memorandum arguing that, given the content of the documents, the Court should find that Abbott had no need for the material in this litigation. Based on the November 9 Order, the United States did not submit documents concerning companies other than Abbott. For example, when objecting to the magistrate's order, the Government described a document relating to TAP's criminal plea relating to its marketing of Lupron.<sup>13</sup> Although this would have been a document covered by the magistrate's August 13 order, the Government did not produce it for *in camera* review in December because it did not fall within the parameters of this Court's subsequent order resolving the parties' objections.

With respect to the manner in which the United States is construing the November 9 Order, the Court is respectfully referred to the memorandum filed with the documents submitted for *in camera* review to the magistrate. (Dkt. 4920) As explained in that memorandum, a substantial portion of the submitted documents were drafts of a 1997 OIG report entitled "Excessive Reimbursement for Prescription Drugs" and a 2001 OIG entitled "Medicaid's Use of Revised Wholesale Prices." The draft versions of these reports were submitted for review because they reference the drug Vancomycin, which is a drug at issue in this litigation. None of the draft versions of the reports, however, make any reference, explicit or otherwise, to Abbott. Under Abbott's reading of the November 9 Order, the United States should have submitted for review not just the documents referencing Vancomycin, but any document relating to antibiotics – which is the "general category" into which Vancomycin falls. Such an interpretation, however, is

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<sup>13</sup> See United States Objections to Aug. 13, 2007 Order by Magistrate Judge Bowler (Dkt. 4697), at 10.

not in accord with either the plain language of the Order or how it should be understood in light of the arguments and objections by Abbott to which the Order responded.

In light of the foregoing, it has been clear, at least since last December, that the Government has *not* construed the November 9 Order to require the submission of only those documents which expressly reference Abbott - as Abbott now claims. Based on the full record relating to the United States' compliance with the November 9 Order, the plain language of the Order itself, and in light of the arguments and assertions which that Order resolved, the magistrate judge correctly denied Abbott's motion for *in camera* submission and her decision should be upheld.

### **III. Conclusion**

For the foregoing reasons, Abbott's Objections to the magistrate judge's Feb. 2, 2008 Orders should be denied.

Respectfully submitted,

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Dated: February 29, 2008

**CERTIFICATE OF SERVICE**

I hereby certify that I have this day caused an electronic copy of the above MEMORANDUM BY THE UNITED STATES IN RESPONSE TO DEFENDANT ABBOTT LABORATORIES INC.'S OBJECTIONS TO MAGISTRATE JUDGE BOWLER'S FEB. 1, 2008 ORDERS to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

Dated: Feb. 29, 2008

/s/  
Justin Draycott